December 8, 2001

MEMORANDUM

Subject: Efficacy Review for 675-55 / Lysol Brand Disinfectant S.A. Cleaner
DP Barcode: D275904
Case No.: 062161

From: Ian Blackwell, Biologist
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Through: Emily Mitchell, Team Leader
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Applicant: Reckitt Benckiser, Inc.

Formulation From Label:

Active Ingredient(s)	% by wt
Citric Acid	2.5
Inert Ingredient(s)	97.5
Total	100.0

I. **BACKGROUND:** Reckitt Benckiser, Inc., has submitted a set of product efficacy studies in support of their product "Lysol Brand Disinfectant S.A. Cleaner". These studies were conducted by ViroMed Biosafety Laboratories. The MRID Numbers are 454311-01 through 454311-06.

The studies are not submitted to support general/broad-spectrum or hospital disinfectant claims (the product is already registered for that), but are intended to support claims of this product as being a sanitizer, a disinfectant against specific bacteria, or, a virucide against specific viruses.

II **Use Directions**

Lysol Brand Disinfectant S.A. Cleaner is a disinfectant, virucide, and sanitizer that is intended for use on washable bathroom (restroom) surfaces and fixtures around the home, in schools, hospitals and other health care facilities and other places. The product is sold as a pump spray. The directions for disinfection state: "To Disinfectant: If surfaces are visibly dirty, follow cleaning directions first; then spray on (apply on) surface until thoroughly wet. Leave for ten minutes. Wipe with a damp cloth or sponge." The directions for cleaning state: "To Clean: Turn nozzle to desired position. Spray 6-8 inches from (apply on) surface to be cleaned until thoroughly wet. Wipe off with clean cloth or sponge. For stubborn stains, allow 15-20 seconds before wiping."

The label also displays the following alternate language for sanitization claims:

- To Sanitize/Deodorize: For hard, non-porous surfaces such as tile, tubs, etc., spray until thoroughly wet. Let stand for 30 seconds before wiping.
- Kills [eliminates] 99.9% of [bacteria][viruses] [germs] on hard, non-porous surfaces in seconds.
- Fast Acting Sanitizer.
- Kills [eliminates] 99.9% of *Escherichia coli* (*E. coli* 0157:H7), *Staphylococcus aureus* (*Staphylococcus*), *Staphylococcus aureus* - MRSA, *Enterococcus faecalis* (VRE), *Enterobacter aerogenes*, Rhinovirus Type 39 and Rotavirus on hard, non-porous surfaces in 30 seconds.

III **Agency Standards for Proposed Claims**

As this product is a disinfectant/virucide/sanitizer, studies must be submitted that demonstrate the efficacy of the product in these areas. For microorganism-specific disinfectant (anti-bacterial) claims, a product must be tested against each microorganism using two different lots or batches of the product. Each lot is to be used against 10 carriers for a total of 20 samples. Killing of the test microorganism

on all carriers is required. Plate count data, on appropriate culture media, must be submitted on each test microorganism to disclose that a concentration of at least 10^4 microorganisms survive the carrier-drying step in order to provide meaningful results.

As per the DIS/TSS -10, when testing products for their ability to sanitize non-food contact surfaces, "Three product samples, representing 3 different preparations, one of which is at least 60 days old, should be tested against each test bacterium on each test surface. The test bacteria are *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae*, aberrant, (ATCC 4352). Enterobacter aerogenes (ATCC 13048 or 15038) may be substituted for *K. pneumoniae*. The results must show a bacterial reduction of at least 99.9% over the parallel control count within 5 minutes."

IV Comments on the Submitted Efficacy Studies

1. MRID 454311-01: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" by Jolene R. Kingston. ViroMed Biosafety Laboratories. Study ID Number 8286. Study Completion Date 2/25/2000.

   The study was conducted to determine the ability of EPA Reg. No. 675-55 to sanitize inanimate, non-food contact surfaces. This study was conducted using *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) as the standard test bacteria. Five percent Fetal Bovine Serum was added to the bacterial culture as a soil load. Sterile carriers were inoculated with 0.03 mL of 48-hour cultures of the test bacteria. As the product is sold as a pre-formulated pump spray, no dilution or other preparation of the test substance was required. For each batch of test substance, five carriers were sprayed at a distance of six to eight inches with three to four strokes at one minute intervals. Each carrier remained in contact with the test substance for 30 seconds at room temperature (23°C). After treatment, each carrier was transferred to 20 mL aliquots of neutralizer in jars. Within 30 minutes after neutralizing the test substance, 1.0 mL and 0.1 mL aliquots of neutralizer solution from each of the jars were plated on blood agar (BAP) in duplicate.

2. MRID Number 454311-02: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" by Brad K. Onstad. ViroMed Biosafety Laboratories. Study ID Number 8242. Study Completion Date 2/18/2000.

   This study was conducted to determine the ability of Lysol Brand Disinfectant S.A. Cleaner to sanitize inanimate, non-food contact surfaces contaminated with Methicillin-Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592). This study was conducted in the same manner as #1, above.

3. MRID Number 454311-03: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" by Jolene R. Kingston. ViroMed Biosafety Laboratories. Study ID Number 8241. Study Completion Date 1/26/2000.

   This study was conducted to determine the ability of Lysol Brand Disinfectant S.A. Cleaner to sanitize inanimate, non-food surfaces contaminated with *Enterococcus faecalis* - VRE (ATCC 51299). This study was conducted in the same manner as #1, above.

4. MRID Number 454311-04: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" by Karen M. Ramm. ViroMed Biosafety Laboratories. Study ID Number 8768. Study Completion Date 5/9/2000.

   This study was conducted to assess the ability of EPA Reg. No. 675-55 to disinfect hard, non-porous surfaces contaminated with Rotavirus (no ATCC Number was included in the report). The study included 10% Fetal Bovine Serum as an organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over three 100 x 15 mm sterile glass petri dishes. The inoculated films were then air-dried. For each lot of disinfectant, separate dried virus films were exposed for 30 seconds at 19°C to the spray disinfectant. The carriers were sprayed with three strokes at a distance of six to eight inches from their surface. The virus films were completely covered with the disinfectant. Following exposure, the plates were scraped with a cell scraper to resuspend the contents of the plate. The virus-disinfectant mixture was then passed immediately through a Sephadex column in order to detoxify the mixture. The filtrate was then titered by serial dilution for infectivity.

5. MRID Number 454311-05: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" by Karen M. Ramm. ViroMed Biosafety Laboratories. Study ID Number 8769. Study Completion Date 4/24/2000.

   This study was conducted to assess the virucidal effectiveness of EPA Reg. No. 675-55 against Rhinovirus type 39, Strain 209 (ATCC Number VR-340) contaminated/inoculated surfaces. The study included 10% Fetal Bovine Serum as an organic soil load. The study was conducted in the same manner as #5 (MRID Number 454311-04) above.

6. MRID Number 454311-06: "Germicidal Spray Products" by Karen M. Ramm. ViroMed Biosafety Laboratories. Study ID Number 8231. Study Completion Date 12/9/1999.

   This study was conducted to evaluate the ability of EPA Reg. No. 675-55 to disinfectant hard, non-porous surfaces contaminated with *Escherichia coli* 0157:H7 (ATCC 43888). A 0.25 mL aliquot of fetal bovine serum was added to

4.75 mL of the broth culture to yield a 5% soil load. Individual glass slide carriers were each inoculated with 0.01 mL of the culture. The slides were dried for 30 minutes. The spray was used Ready-To-Use (RTU) as it was received from the sponsor. For each lot of the test material, 10 carriers were sprayed individually with the test material with three strokes at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the germicide for 30 seconds at room temperature (22°C). Following spray treatment, the remaining test liquid was drained off. Each treated carrier was then transferred to 20 mL aliquots of Letheen Broth. Following incubation, the medium in each tube was observed for the presence of visible growth.

V Results

MRID 454311-01		
Organism	Batch #	Percent Reduction
Staphylococcus aureus (ATCC 6538)	655-052	> 99.9
	665-054	> 99.9
	571-171	> 99.9
Enterobacter aerogenes (ATCC 13048)	655-052	> 99.9
	655-054	> 99.9
	571-171	> 99.9

MRID 454311-02		
Organism	Batch #	Percent Reduction
Staphylococcus aureus (MRSA) (ATCC 33592)	665-054	> 99.9
	571-171	> 99.9

MRID 454311-03		
Organism	Batch #	Percent Reduction
Enterococcus faecalis - VRE (ATCC 51299)	665-054	> 99.9
	571-171	> 99.9

MRID Number 454311-04			
Dilution of Virus	Dried Virus Control	Rotavirus + Batch 571-171	Rotavirus + Batch 665-052
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0
10^{-1}	+ + + +	T T T T	T T T T
10^{-2}	+ + + +	T T T T	T T T T
10^{-3}	+ + + +	0 0 0 0	0 0 0 0
10^{-4}	+ + + +	0 0 0 0	0 0 0 0
10^{-5}	+ + + +	0 0 0 0	0 0 0 0
10^{-6}	+ + + 0	0 0 0 0	0 0 0 0
10^{-7}	0 0 + 0	0 0 0 0	0 0 0 0
10^{-8}	0 0 + 0	0 0 0 0	*0 0 0 0

Note: T = toxic; + = virus recovered; 0 = no virus recovered.

* - This study shows complete inactivation of Rotavirus beyond the cytotoxic level.

MRID Number 454311-05			
Dilution of Virus	Dried Virus Control	Rhinovirus + Batch 665-052	Rhinovirus + Batch 571-171
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0
10^{-1}	+ + + +	T T T T	T T T T
10^{-2}	+ + + +	0 0 0 0	0 0 0 0
10^{-3}	+ + + +	0 0 0 0	0 0 0 0
10^{-4}	+ + + +	0 0 0 0	0 0 0 0
10^{-5}	0 + 0 0	0 0 0 0	0 0 0 0
10^{-6}	+ + + 0	0 0 0 0	0 0 0 0
10^{-7}	0 0 0 0	0 0 0 0	*0 0 0 0

* - This study shows complete inactivation of Rotavirus beyond the cytotoxic level.

MRID Number 454311-06			
Test Organism	Batch	Carrier Bacterial Count	Percent Reduction
Escherichia coli 0157:H7 (ATCC 43888)	Control	1.2×10^4	n/a
	665-052	0	100%
	571-171	0	100%

VI Conclusions

1. MRID Number 454311-01: The submitted efficacy data supports the use of the test material, Formula Number 592-063, as an effective sanitizer for inanimate non-food contact surfaces when used as an undiluted spray with a contact time of 30 seconds at room temperature in the presence of a 5% soil load. However, this study is currently not acceptable to support the registration product as it does not state that it was conducted on EPA Reg. No. 675-55, but that it was conducted using "Formula Number 592-063." The registrant needs to clarify whether or not Formula Number 592-063 and Lysol Brand Disinfectant S.A. Cleaner are the same material.

2. MRID Number 454311-02: The submitted efficacy data support the use of the test material, Formula Number 592-063, as an effective sanitizer for inanimate non-food contact surfaces contaminated with *Staphylococcus aureus* (MRSA) (ATCC 33592) when used as a spray with a contact time of 30 seconds at room temperature in the presence of a 5% soil load. However, this study is currently not acceptable to support the registration product as it does not state that it was conducted on EPA Reg. No. 675-55, but that it was conducted using "Formula Number 592-063." The registrant needs to clarify whether or not Formula Number 592-063 and Lysol Brand Disinfectant S.A. Cleaner are the same material. Also, this study is not acceptable because it does not contain an antibiotic resistance profile for the test organism.

3. MRID Number 454311-03: The submitted efficacy data support the use of the test material, Formula Number 592-063, as an effective sanitizer for inanimate non-food contact surfaces contaminated with *Enterococcus faecalis* - VRE (ATCC 51299) when used as a spray with a contact time of 30 seconds at room temperature in the presence of a 5% soil load. However, this study is currently not acceptable to support the registration product as it does not state that it was conducted on EPA Reg. No. 675-55, but that it was conducted using "Formula Number 592-063." The registrant needs to clarify whether or not Formula Number 592-063 and Lysol Brand Disinfectant S.A. Cleaner are the same material. Also, this study is not acceptable because it does not contain an antibiotic resistance profile for the test organism.

4. MRID Number 454311-04: When used as packaged, Formula 592-063 was an effective virucide against Rotavirus when used in conjunction of a 30 second exposure and at room temperature in the presence of a 10% soil load. However, this study is currently not acceptable to support the registration product as it does not state that it was conducted on EPA Reg. No. 675-55, but that it was conducted using "Formula Number 592-063." The registrant needs to clarify whether or not Formula Number 592-063 and Lysol Brand Disinfectant S.A.

Cleaner are the same material. Also, this report did not include the ATCC Number of the strain of Rotavirus used in the study.

5. MRID Number 454311-05: When tested undiluted (as packaged), at 20°C, with a 30 second exposure in the presence of 10% Fetal Bovine Serum, Formula Number 592-063, was an effective virucide against Rhinovirus type 39, Strain 209 (ATCC VR-340). However, this study is currently not acceptable to support the registration product as it does not state that it was conducted on EPA Reg. No. 675-55, but that it was conducted using "Formula Number 592-063." The registrant needs to clarify whether or not Formula Number 592-063 and Lysol Brand Disinfectant S.A. Cleaner are the same material.

6. MRID Number 454311-06: When test undiluted, at 22°C in the presence of a 5% soil load, Formula 592-063 was an effective disinfectant against *Escherichia coli* 0157:H7 (ATCC 43888). However, this study is currently not acceptable to support the registration product as it does not state that it was conducted on EPA Reg. No. 675-55, but that it was conducted using "Formula Number 592-063." The registrant needs to clarify whether or not Formula Number 592-063 and Lysol Brand Disinfectant S.A. Cleaner are the same material.

VII Recommendations:

1. The requests to add labeling claims against any bacteria or viruses based on the studies included in this submission are denied. None of the six studies included in this submission (D275904) identified the test material as either EPA Reg. No. 675-55 or Lysol Brand Disinfectant S.A. Cleaner. The test material in each of these studies was identified as "Formula Number 592-063". Due to this problem, none of the six submitted studies can be accepted at this time. In order for each of the studies to be reconsidered, the registrant must clarify the identity of Formula Number 592-063, and its relationship to EPA Reg. No. 675-55.

2. MRID Number 454311-04: This study was conducted against Rotavirus. The study is not currently acceptable because the strain of Rotavirus was not identified. In order to have the status of this study reconsidered, the registrant must provide an identification number (such as an ATCC Number) for the strain of Rotavirus used in this study in addition to the identification of the test material used.